

## FINAL NIH STATEMENT ON SHARING RESEARCH DATA

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NOTICE: NOT-OD-03-032

National Institutes of Health ((NIH))

As part of NIH's long-standing policy to share and make available to the public the results and accomplishments of the activities that it funds, NIH announced and invited comments on a draft statement about the sharing of final research data on March 1, 2002.

Since that time, NIH has received and reviewed many thoughtful comments from a range of scientific organizations and over 150 individuals. Additionally, during the comment period, HHS published final modifications for the STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION, the "Privacy Rule," of the Health Insurance Portability and Accountability Act (HIPAA), available at <http://www.hhs.gov/ocr/>

The Privacy Rule is a federal regulation that governs how certain health care providers, health care clearinghouses, and health plans, known as "covered entities," use and disclose identifiable health information. NIH has carefully considered the comments and the Privacy Rule, and issues the following statement on data sharing:

NIH reaffirms its support for the concept of data sharing. We believe that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. The NIH endorses the sharing of final research data to serve these and other important scientific goals. The NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. Starting with the October 1, 2003 receipt date, investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why data sharing is not possible.

As indicated above, all investigator-initiated applications with direct costs greater than \$500,000 in any single year will be expected to address data sharing in their application. Applicants are encouraged to discuss their data sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application as described at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>

Applicants are reminded that agreement to accept assignment of applications over \$500,000 must be obtained at least six weeks in advance of the anticipated submission date. Instructions related to the data sharing policy as it is applied to applications and proposals responding to a specific Request for Application (RFA) or Request for

Proposals (RFP) will be described in the specific solicitation. In some cases, Program Announcements (PA) may request data sharing plans for applications that are less than \$500,000 direct costs in any single year. Reviewers will not factor the proposed data-sharing plan into the determination of scientific merit or priority score. Program staff will be responsible for overseeing the data sharing policy and for assessing the appropriateness and adequacy of the proposed data-sharing plan.

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule. As NIH stated in the March 1, 2002 draft data sharing statement (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-035.html>), the rights and privacy of people who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects. When data sharing is limited, applicants should explain such limitations in their data sharing plans.

The final NIH statement on data sharing is largely the same as stated in the March 1, 2002 draft with the following exceptions:

- The effective start date has been changed from January 1, 2003 to October 1, 2003 receipt date.
- This policy applies to applicants seeking \$500,000 or more in direct costs in any year of the project period. Such applicants are expected to contact IC program staff prior to submission and are also expected to include a data-sharing plan in their application stating how they will share the data or, if they cannot share the data, why not. Applicants responding to an RFA or RFP will find instructions related to data sharing in the specific announcement.
- Several groups and individuals objected to sharing of research data prior to publication. As noted earlier, NIH recognizes that the investigators who collect the data have a legitimate interest in benefiting from their investment of time and effort. We have therefore revised our definition of "the timely release and sharing" to be no later than the acceptance for publication of the main findings from the final data set. NIH continues to expect that the initial investigators may benefit from first and continuing use but not from prolonged exclusive use.

For more information on data sharing, please see our website at [http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/)